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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,040	07/21/1999	PETER MOSE LARSEN	2012.0390004	9201

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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/297,040

Applicant(s)

MOSE LARSEN ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9,12-18,20,21 and 24-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,9,12-18,20,21,24-27 and 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of claims

Claims 1-5, 9, 12-18, 20-21 and 24-39 are pending.

Status of the current Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 6 August 2004 has been entered. Also, Applicant requests petition for extension of time of one-month has been entered.

Applicant's response filed 6 August 2004, which cancels claims 6-8, 10-11, 19 and 22-23, and adds claims 28-39 has been entered. Also, Applicants' request for extension of time of three months has been entered. Claims 1-5, 9, 12-18, 20-21 and 24-27 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention (see the office action mailed 17 June 2003).

Claims 34-39 are directed to using the polynucleotide for preventing a diabetes state. Since Applicants have elected the protein composition and a method of using said protein for preventing or treating a diabetes state for examination but NOT a method of using a polynucleotide encoding said protein for the same, and since the method claims of using the protein and the method claims of using the polynucleotide are different/distinct from each other in methodologies, starting material, therapeutic ingredients, steps and/or outcome, claims 34-39

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are withdrawn from further consideration as being drawn to a non-elected invention. Thus, claims 28-33 are examined in this Office action.

Claim objection

Claim 33 is objected under 37 CFR 1.75 as being a substantial duplicate of claim 32 because it is well-known that insulin dependent diabetes mellitus (melitis) is type I diabetes. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP §706.03(k). Also, Applicant is advised that should claim 32 or 33 be found allowable, claim 33 or 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe a method of preventing a diabetes state in a subject comprising administering to said subject a protein comprising amino acid sequence which has at

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least 90% or 95% sequence identity to the instant SEQ ID NO:4 (human galectin-3). Thus, applicants are not in possession of the claimed method.

While applicants may wish to amend the claims in such a way that the variant of 95% or 90% sequence identity to full-length SEQ ID NO:4 which has assayable function, nevertheless such the amendment still cannot overcome the enablement rejection to the claimed method (see below).

Claims 28- 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is directed to a method of preventing or treating a subject suffering from a diabetes disorder comprising administering to the subject a protein composition comprising the full-length SEQ ID NO:4 or a sequence having at least 90% or 95% sequence identity to SEQ ID NO:4. In Example 8, the specification states that galectin-3 expression was down-regulated at onset of IDDM. Based on this statement, the galectin-3 has a putative role in treating or/and preventing a diabetes disorder. It should be noted that there are a large number of proteins involved in the development of the diabetes disorder. The art teaches that down-regulation of a protein does not necessarily correlate with a potential of said protein being used for treating or preventing the diabetes. For instance, tumor necrosis factor-alpha (TNF- α) has been known to induce a diabetes state; yet, the TNF- α expression level which is at least not elevated but appears to be down-regulated in patients suffering from a diabetes (see Table 1 of

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Bluher, M. et al. reference: *Diabetes Care* (2001), 24, 328-334). This suggests that there necessarily is no correlation between down-regulation of a protein (expression regulation) and therapeutic use (treatment or prevention) of said protein. The specification at best suggests that the galectin-3 expression regulation occurs when diabetes develops but not adequately disclose how to prevent said diabetes using the claimed composition. Thus, given the unpredictability of the field of the invention, the relative lack of information of human galectin-3 protein having an ability of preventing a diabetes, one skilled in the art would be unable to practice the claimed invention without the exercise of undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites “diabetes melitis”; the recitation is not apparent as to whether or not the it refers to “diabetes mellitus”. If yes, it is advised to be changed to “diabetes mellitus” because the former is not a widely-accepted phrase. Note that the specification does not provide definition of the phrase.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The

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examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242 or 703-872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Karen Cochrane Carlson RSD

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

swl

Samuel Wei Liu, Ph.D.

September 14, 2004